



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,900	03/07/2002	Muralidhara Padigaru	21402-290C (CURA	1049

7590 10/28/2003

Ivor R. Elrifi
Mintz, Levin, Cohn, Ferris,
Glovsky and Popeo, P.C.
One Financial Center
Boston, MA 02111

EXAMINER

KAPUST, RACHEL B

ART UNIT	PAPER NUMBER
----------	--------------

1647

DATE MAILED: 10/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/092,900	Applicant(s) PADIGARU ET AL.	
	Examiner Rachel B. Kapust	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-26 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4, drawn to an isolated polypeptide, classified in class 530, subclass 350.
- II. Claims 5 and 6, drawn to a method for determining the presence or amount of a polypeptide, classified in class 435, subclass 7.1 and class 424, subclass 9.1.
- III. Claims 7-9, drawn to a method of identifying binding agents, classified in class 436, subclass 503 and class 424, subclass 9.2.
- IV. Claims 10-11, drawn to a method for screening for a modulator of polypeptide activity, classified in class 800, subclass 3.
- V. Claim 12, drawn to a method for modulating the activity of a polypeptide, classified in class 514, subclass 2.
- VI. Claims 13-22, drawn to isolated nucleic acid molecules, vectors comprising nucleic acid molecules, and host cells comprising vectors, classified in class 435, subclasses 69.1 and 320.1.
- VII. Claims 23-26, drawn to a method for determining the presence or amount of a nucleic acid molecule, classified in class 435, subclass 6 and class 424, subclass 9.1.

The inventions are distinct, each from the other because of the following reasons:

Group I and Groups II-V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptides of Group I can be used in a variety of methods such as purification assays, ligand binding assays, or other diagnostic assays. Groups I and VI

Art Unit: 1647

are not related. The polypeptides of Group I are composed of amino acids linked in peptide bonds that are arranged spatially in a number of different tertiary structures including alpha helices, beta-pleated sheets, and hydrophobic loops (transmembrane domains). The polynucleotides of Group VI are composed of nucleotides linked in phosphodiester bonds and arranged in space as a double helix. Group I is not related to Group VII. The polypeptides of Group I cannot be used in the method of Group VII.

Groups II-V are distinct, each from the other. The methods are drawn to different conditions and thus have different goals and different outcome measures. Groups II-V are not related to Group VI. The polynucleotides of Group VI cannot be used in the methods of Groups II-V. Groups II-V are not related to Group VII. The methods require different reagents and different method steps.

Group VI and Group VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polynucleotides of Group VI can be used in a variety of methods such as purification assays, ligand binding assays, or other diagnostic assays.

Further Restriction

Groups I-V read on the following unrelated groups (subgroup A-VVVVV):

Sub-Group	SEQ ID NO	Sub-Group	SEQ ID NO	Sub-Group	SEQ ID NO	Sub-Group	SEQ ID NO
A	2	GG	108	MMM	192 and 194	SSSS	274, 276, and 278
B	4, 6, 8, and 10	HH	110	NNN	196	TTTT	280
C	12	II	112	OOO	198	UUUU	282
D	14	JJ	114 and 116	PPP	200	VVVV	284
E	16	KK	118 and 120	QQQ	202	WWWW	286
F	18	LL	122	RRR	204	XXXX	288
G	20	MM	124	SSS	206	YYYY	290
H	22 and 24	NN	126	TTT	208	ZZZZ	292, 294, and 296
I	26 and 28	OO	128	UUU	210	AAAAA	298
J	30 and 32	PP	130 and 132	VVV	212	BBBBB	300
K	34 and 36	QQ	134	WWW	214	CCCCC	302
L	38	RR	136	XXX	216	DDDDD	304

Art Unit: 1647

M	40 and 42	SS	138 and 140	YYY	218	EEEE	306
N	44, 46, 48, 50, and 52	TT	142	ZZZ	220	FFFF	308
O	54, 56, and 58	UU	144 and 146	AAAA	222	GGGG G	310
P	60	VV	148	BBBB	224	HHHH	312
Q	62, 64, 66, and 68	WW	150	CCCC	226 and 228	IIII	314
R	70	XX	152	DDDD	230	JJJJ	316 and 318
S	72	YY	154	EEEE	232	KKKK	320 and 322
T	74	ZZ	156	FFFF	234 and 236	LLLL	324
U	76	AAA	158	GGGG	238	MMMM M	326 and 328
V	78	BBB	160	HHHH	240	NNNN	330
W	80	CCC	162	IIII	242	OOOO O	332
X	82, 84, and 86	DDD	164 and 166	JJJJ	244 and 246	PPPP	334
Y	88	EEE	168 and 170	KKKK	248	QQQQ Q	336
Z	90 and 92	FFF	172, 174, and 176	LLLL	250, 252, 254, 256, and 258	RRRR	338
AA	94	GGG	178 and 180	MMMM	260	SSSS	340
BB	96	HHH	182	NNNN	262	TTTT	342
CC	98	III	184	OOOO	264 and 266	UUUU	344 and 346
DD	100 and 102	JJJ	186	PPPP	268	VVVV	348
EE	104	KKK	188	QQQQ	270	XXXX	350 and 352
FF	106	LLL	190	RRRR	272	YYYY	354 and 356

If Group I, II, III, IV or V is elected, Applicants must further elect one of the above-listed subgroups for further prosecution. Applicants are advised that examination will be restricted to only the elected sequence(s) corresponding to the elected subgroup, and this is not to be construed as a species election.

Art Unit: 1647

Groups VI and VII read on the following unrelated groups (subgroups a-yyyyy):

Sub-Group	SEQ ID NO	Sub-Group	SEQ ID NO	Sub-Group	SEQ ID NO	Sub-Group	SEQ ID NO
a	1	gg	107	mmm	191 AND 193	ssss	273, 275, and 277
b	3, 5, 7, and 9	hh	109	nnn	195	tttt	279
c	11	ii	111	ooo	197	uuuu	281
d	13	jj	113 and 115	ppp	199	vvvv	283
e	15	kk	117 and 119	qqq	201	wwww	285
f	17	ll	121	rrr	203	xxxx	287
g	19	mm	123	sss	205	yyyy	289
h	21 and 23	nn	125	ttt	207	zzzz	291, 293, and 295
i	25 and 27	oo	157	uuu	209	aaaaa	297
j	29 and 31	pp	129 and 131	vvv	211	bbbbbb	299
k	33 and 35	qq	133	www	213	ccccc	301
l	37	rr	135	xxx	215	dddddd	303
m	39 and 41	ss	137 and 139	yyy	217	eeeeee	305
n	43, 45, 47, 49, and 51	tt	141	zzz	219	fffff	307
o	53, 55, and 57	uu	143 and 145	aaaa	221	gggggg	309
p	59	vv	147	bbbb	223	hhhhh	311
q	61, 63, 65, and 67	ww	149	cccc	225 and 227	iiii	313
r	69	xx	151	dddd	229	jjjj	315 and 317
s	71	yy	153	eeee	231	kkkkk	319 and 321
t	73	zz	155	ffff	233 and 235	llll	323
u	75	aaa	157	gggg	237	mmmmm	325 and 327
v	77	bbb	159	hhhh	239	nnnnn	329
w	79	ccc	161	iiii	241	ooooo	331
x	81, 83, and 85	ddd	163 and 165	jjjj	243 and 245	ppppp	333
y	87	eee	167 and 169	kkkk	247	qqqqq	335
z	89 and 91	fff	171, 173, and 175	llll	249, 251, 253, 255, and 257	rrrrr	337
aa	93	ggg	177 and 179	mmmm	259	sssss	339
bb	95	hhh	181	nnnn	261	ttttt	341
cc	97	iii	183	oooo	263 and 265	uuuuu	343 and 345
dd	99 and 101	jjj	185	pppp	267	vvvvv	347
ee	103	kkk	187	qqqq	269	xxxxx	349 and 351
ff	105	lll	189	rrrr	271	yyyyy	353 and 355

If Group VIII, IX or X is elected, Applicants must further one of the above-listed subgroups for further prosecution. Applicants are advised that examination will be restricted to only the elected sequence(s) corresponding to the elected subgroup, and this is not to be construed as a species election.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. For example, if the elected product of Group I is found allowable, the methods of Groups II-V may be rejoined. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Because these inventions are distinct and/or unrelated for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the searches required for the different groups are different from each other, restriction for examination purposes as indicated is proper.


Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel B. Kapust whose telephone number is (703) 305-0634. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

RBK


JANET ANDREWS
PATENT EXAMINER